

## Nuclear Regulatory Commission

## § 30.32

of this section or equivalent regulations of an Agreement State.

[34 FR 6653, Apr. 18, 1969, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993]

### § 30.21 Radioactive drug: Capsules containing carbon-14 urea for “in vivo” diagnostic use for humans.

(a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in Section 81 of the Act and from the regulations in this part and part 35 of this chapter provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1  $\mu$  Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for “in vivo” diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to part 35 of this chapter.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to § 32.21 of this chapter.

(d) Nothing in this section relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

[62 FR 63640, Dec. 2, 1997]

## LICENSES

### § 30.31 Types of licenses.

Licenses for byproduct material are of two types: General and specific.

(a) The Commission issues a specific license to a named person who has filed an application for the license under the provisions of this part and parts 32 through 36, and 39.

(b) A general license is provided by regulation, grants authority to a person for certain activities involving byproduct material, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular per-

son. However, registration with the Commission may be required by the particular general license.

[65 FR 79187, Dec. 18, 2000]

### § 30.32 Application for specific licenses.

(a) A person may file an application on NRC Form 313, “Application for Material License,” in accordance with the instructions in § 30.6 of this chapter. Information contained in previous applications, statements or reports filed with the Commission or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific.

(b) The Commission may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Commission to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for license filed pursuant to the regulations in this part and parts 32 through 35 of this chapter will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with regulations of the Commission as to applications for such licenses.

(e) Each application for a byproduct material license, other than a license exempted from part 170 of this chapter, shall be accompanied by the fee prescribed in § 170.31 of this chapter. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in § 170.31 of this chapter.

(f) An application for a license to receive and possess byproduct material for the conduct of any activity which the Commission has determined pursuant to subpart A of part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility